

## **REMARKS**

The Examiner has rejected Claims 1 through 19 (claims 13 through 19 being renumbered as 13 through 20). Claims 20 through 33 have been renumbered as claims 21 through 34, and are withdrawn from consideration as being directed to the non-elected invention. Claims 1 through 20 are pending. No new matter has been added by way of the amendments herein above.

### **Restriction Requirement under 35 U.S.C. §121:**

The Examiner has required election under 35 U.S.C. 121 for one of the following groups of inventions:

Group I, Claims 1 through 19, drawn to the surgical cement preparation system (class 206, subclass 571)

Group II, Claims 20 through 34, drawn to the process for preparing opacified cement (class 366, subclass 189).

Applicants hereby affirm the election of Group I, claims 1 through 19 (20), said election having been made with traverse, during a telephone conference with Examiner Jerry Johnson on May 4, 2005. Claims 20 (21) are withdrawn from consideration as being drawn to the non-elected invention. Applicants hereby reserve the right to pursue the non-elected invention and corresponding claims by way of continuing application.

The Groups set forth in the Examiner's restriction requirement are based on the basic division between system and kit claims, and the claims directed to the process of preparing the opacified cement. The groupings, however, make the separation between

claims 1 through 19 and 20 through 34. According to Applicants' application copy, however, the first process claim is claim 21 (hence the above parentheticals in the claim status summary). Until the claim numbers are reconciled with the Examiner, Applicants will attempt to refer to the claims as they apparently appear in the Examiner's application copy.

Applicants traverse the restriction between Groups I and II for the following reasons. The Examiner argues that the product as claimed can be used in a materially different process, "such as mixing the ingredients in the mixing vial with the spatula." In attempting to justify the restriction requirement on the basis of distinctness, the Examiner has apparently overlooked then fact that Applicants' process claim and the recited steps within are dependent upon the particular components of the claimed system. It is Applicants' position that the claimed process and the system/kit claims would require substantially co-extensive search efforts into the prior art, and not create an undue burden on the Examiner's behalf. Applicants therefore request that Group II be regrouped with Group I, and that all the claims be examined on the merits.

#### **Objection to Claims:**

The Examiner has objected to the presence of two claim "13s" in the application. The Examiner has also objected to claim 19 based on incorrect dependency as depending upon itself.

Applicants have renumbered the second-appearing claim 13 as claim 14, and renumbered the subsequent claims in consecutive order. The total number of claims in the application is 34.

Applicants have now renumbered claim 19 as claim 20. Consequently, the recited dependency upon claim 19 is now correct.

The Examiner's concerns have not been fully addressed.

**Rejections under 35 U.S.C. §103:**

The Examiner has rejected claims 1, 7, 8 and 10 under 35 U.S.C. §103(a) as being unpatentable over Chan U.S. Patent No. 6,516,977 in view of Howson et al. U.S. Patent No. 4,834,152 and Ronk U.S. Patent No. 5,951,160. Applicants respectfully traverse this rejection for the following reasons.

The Examiner argues that Chan discloses a surgical cement preparation system for combining liquid and powder ingredient together comprising a needle and syringe assembly with a closed distal tip and lateral side opening, and a mixing vial with a removable cap having a secondary cap.

Chan teaches a substantially different mixing system for surgical cement than that of Applicants' invention. First of all, Chan is designed and structured as a mixing apparatus structured for maintaining vacuum conditions. Applicants' system, on the other hand, does not employ – nor is it structured to cooperate with – an integrated vacuum system.

The Examiner argues that Chan teaches a removable cap with a second opening. The Examiner further alleges that “cap 80” constitutes a teaching of a cap over the second opening in a manner equivalent to Applicants' cap assembly. Clearly, the Examiner has applied an inappropriate amount of creative “gap-filling” here. The Examiner is referred to feature 80 in Chan, which is in reality defined by Chan as a self-sealing “injection port” (see column 6, lines 6 through 12, for example). This is neither

structurally nor functionally “equivalent” to Applicants’ removable secondary cap structure. In fact, the Examiner has fabricated the feature even being referred to as a “cap” by Chan.

As far as the needle having closed tip and a lateral opening and the Examiner’s referral to Ronk, the needle component is part of an overall claimed system. Applicants do not allege that a closed tip needle with lateral constitutes, by itself, a patentable invention. This structure must be viewed within the context of the claimed system.

The Examiner then relies upon Howson for a teaching of a second cap over a first cap. The Examiner then argues that one of ordinary skill in the art would have found the claimed invention to be obvious because the Howson cap would “provide the same benefits as the cap currently used in Chan”.

The Howson reference pertains to a storage receptacle. Again, Applicants are not claiming a first and second cap arrangement alone as the invention. The Howson “connector cap” 45 is within the context of the reference, in which no teaching is seen that fairly teaches or suggests a cement mixing system – the relevant technological context of Applicants’ invention.

The Examiner has not presented a collection of teachings, alone or in combination, that would have lead one of ordinary skill in the art to the claimed invention. Furthermore, it is not understood by Applicants why one of ordinary skill in the relevant orthopedic cement mixing art, would have been motivated in a sensible manner to combine teachings that pertain to a *storage* container cap arrangement, with a sports ball inflation mechanism (needle) that, would be used in conjunction with a cement mixing system. Applicants’ claimed system constitutes a patentable improvement within

the medical/orthopedic cement mixing technology, which is where “one of ordinary skill” would be positioned. The Examiner has thus not presented a case of obviousness within the proper meaning of 35 U.S.C. §103.

Given the above, the claimed invention is not unpatentable over the references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

The Examiner has rejected claim 9 under 35 U.S.C. §103(a) as being unpatentable over Chan U.S. Patent No. 6,516,977 in view of Howson et al. U.S. Patent No. 4,834,152 and Ronk U.S. Patent No. 5,951,160, further in view of Miller U.S. Patent No. 6,783,515. Applicants respectfully traverse this rejection for the following reasons.

The shortcomings of the Chan, Howson and Ronk references have been discussed in the above remarks to the rejection under 35 U.S.C. §103, and are likewise applicable here and repeated herein. The Examiner further relies upon Miller for teaching of the use of polypropylene with surgical cement. Again, Applicants are not pursuing the patentability of polypropylene used to contain PMMA by itself. This combination of references fails to render Applicants’ claimed invention obvious – and shares the absence of motivation to combine – as the combination of Chan, Howson and Ronk discussed above.

Given the above, the claimed invention is not unpatentable over the references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

The Examiner has rejected claims 2, 5, 6, 11 through 13, 15 through 18 under 35 U.S.C. §103(a) as being unpatentable over Chan U.S. Patent No. 6,516,977 in view of Howson et al. U.S. Patent No. 4,834,152 and Ronk U.S. Patent No. 5,951,160, further in view of Bonitati et al. U.S. Patent No. 5,586,821, Harrod U.S. Patent No. 4,526,303, Porter U.S. Patent No. 3,211,195 and Hughes et al. U.S. Patent No. 6,364,519.

Applicants respectfully traverse this rejection for the following reasons.

The shortcomings of the Chan, Howson and Ronk references have been discussed in the above remarks to the rejection under 35 U.S.C. §103, and are likewise applicable here and repeated herein. Bonitati is relied on by the Examiner for a teaching of a kit with a funnel for administering cement ingredients into a mixing chamber. The Examiner further relies on Harrod for a teaching of a funnel for administering mixed cement into an applicator. Finally, the Examiner relies on Solomon for a funnel used with a mixing chamber and applicator. The Examiner then turns to Porter for an adaptable funnel.

The Examiner concludes that:

1. funnels are well known in this art for mixing cement ingredients
2. funnels are known to administer mixed cement into applicators
3. single funnels that can mate with various sized containers are known

that one of ordinary skill would have found providing a such a funnel that could be used for both the cement mixing system and delivery to the applicator would have been obvious.

There is no teaching or suggestion in Bonitati to structure a single funnel to be compliant and *securely attach* to more than one container included within a single kit. Harrod uses a funnel with a single *container*. Solomon has a funnel that is used with a

single dual function container. Even the combination of these references do not arrive at the adaptable single funnel used with two or more different sized containers within a single cement preparation system wherein the funnel securely attaches to such to permit hands-free usage of the funnel.

The Examiner relies on Hughes for a teaching of a vial which accommodates a liquid monomer container. The Examiner then attempts to supplement by Official Notice that fragile vials in containers with removable caps is common to assure against their breakage. The Examiner then goes on to further argue that although none of the references teach a liquid monomer vial that can be returned to another container, such is a common way to protect vials in transit, Hughes “inherently discloses” that the first vial is compatible with the monomer because the liquid monomer and powder can be mixed within the first vial.

Again, Applicants’ claimed system affords the advantage of 1) protecting the monomer container until presentation, and 2) providing sealed disposal storage for the remaining liquid (and associated fumes). This vial and container subsystem contributes to the patentable attributes of the overall system. Applicants are not alleging the patentability of this subsystem by itself.

The mere fact that the Examiner has had to cite (cut-and-paste teachings) of so many individual references despite their differences in order to allegedly establish “obviousness” of the claimed invention actually speaks to the nonobviousness of Applicants’ invention. The Examiner should perhaps consider secondary evidence of nonobviousness by virtue of the fact that if one of ordinary skill in the art would have found the combination so obvious, why is the prior art cited by Applicants and the

Examiner absent a single reference containing them within a single system?

The Examiner has filled so many logical and technological gaps in teachings of these references with inappropriate hindsight and creativity that it is clear that should these references had been placed in front of one of ordinary skill in the orthopedic cement art and not knowing about Applicants' invention, it is not probable that one of ordinary skill would have been lead or motivated by them to arrive at Applicants' invention. This evidences that the Examiner's determination of one of ordinary skill in the art is clearly one guided by advance knowledge of Applicants' invention. Therefore, the Examiner's rejection has its foundation on an inappropriate level of hindsight for obviousness purposes.

Applicants have assembled operational shortcomings and problems of conventional cement preparation systems and discovered structural and functional solutions to these problems within a single system. Applicants explain the advantages of the invention throughout the specification. The prior art applied by the Examiner does not fairly teach or suggest that which has been accomplished by Applicants in a given reference or even reasonable combination of the references.

Given the above, the claimed invention is not unpatentable over the references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

The Examiner has rejected claims 2, 5, 6, 11 through 13, 15 through 18 under 35 U.S.C. §103(a) as being unpatentable over Chan U.S. Patent No. 6,516,977 in view of Howson et al. U.S. Patent No. 4,834,152 and Ronk U.S. Patent No. 5,951,160, further in



view of Bonitati et al. U.S. Patent No. 5,586,821, Harrod U.S. Patent No. 4,526,303, Porter U.S. Patent No. 3,211,195 and further in view of Murphy U.S. Patent No. 6,273,916. Applicants respectfully traverse this rejection for the following reasons.

The shortcomings of the Chan, Howson, Ronk, Bonitati, Harrod and Porter references have been discussed in the above remarks to the rejection under 35 U.S.C. §103, and are likewise applicable here and repeated herein.

The Examiner further relies upon Murphy for teachings of 1) barium opacifier with PMMA surgical cement, concluding that it would have been obvious to include such in a cement mixing system system, and 2) spatula for mixing that would “clearly be sufficiently small” to fit within a funnel Applicants’ claimed manner.

Applicants are at a loss to see where in Murphy the Murphy kit includes a “funnel” that this spatula would “clearly fit into”. Clearly, this is exclusively within the Examiner’s imagination, and at least within an inappropriate level of hindsight to support a proper rejection on obviousness grounds. There necessarily cannot be a sensible motivation to combine a spatula of Murphy in the absence of any teaching or suggestion to do so with a funnel specifically structured to securely fit onto at least two different-sized containers – especially when one considers that the “container” of Murphy (numerical reference 86) is a mixing *bowl*.

Given the above, the claimed invention is not unpatentable over the references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

**Conclusion:**

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Dated: Sept 14 2005

Respectfully submitted,



Andrew G. Rozycki, Reg. No. 36,406  
Attorney for Applicants  
Cardinal Health, Inc.  
7000 Cardinal Place  
Dublin, Ohio 43017  
Tel. (614) 757-7413  
Fax (614) 757-2243